



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
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DASG-HCA

31 August 2005

MEMORANDUM FOR Commanders of Units or Activities Executing Force Health Protection Measures

SUBJECT: Compliance with Emergency Use Authorization (EUA) Conditions for Anthrax Vaccine Immunization Program (AVIP)

1. References:

a. Deputy Secretary of Defense, Memorandum, Subject: Resumption of the Anthrax Vaccine Immunization Program Under Emergency Use Authorization (EUA), 25 Apr 05.

b. Under Secretary of Defense (Personnel & Readiness), Memorandum, Subject: Implementation of Resumption of the Anthrax Vaccine Immunization Program Under Emergency Use Authorization (EUA), 29 Apr 05.

2. Initial and Ongoing Compliance. In accordance with references cited above, commanders of units or activities involved with immunizations will complete the compliance agreement (Attachment 1), and checklist (Attachment 2), and then report to the Military Vaccine (MILVAX) Agency weekly on their state of compliance (Attachment 3). The MILVAX Agency will acknowledge the compliance agreement and authorize vaccinations to begin, subject to any local requirements. The weekly report also may be submitted simultaneously to other elements in the unit's or activity's chain of command. The report shall include the following items.

a. Whether or not anyone was required to receive anthrax vaccination against their will, or without being informed of the option to refuse, or otherwise in violation of the option to refuse.

b. In any case in which vaccinations were given without an option to refuse, the report shall include a full explanation of the circumstances involved. Also describe the remedy(ies) to be implemented to prevent a recurrence.

3. Reporting.

a. The commander, deputy commander, officer-in-charge (OIC), or other knowledgeable officer with responsibility for immunization operations will approve the weekly report as the "approving authority" (Attachment 3). [USAF: Clinic OIC prepares report; medical unit commander approves report. USMC: See instructions in governing

MARADMIN message.] For ships or other isolated units where an independent-duty corpsman is the senior medical staff member, the corpsman may submit the approving authority-approved report. Within U.S. Central Command (CENTCOM), reporting channels may be modified to meet operational conditions; CENTCOM will issue specific instructions.

b. If a unit or activity fails to report, MILVAX Agency will contact the alternate points of contact listed on the compliance agreement. If necessary, the MILVAX Agency will contact the appropriate Surgeon General's Office. Vaccine supply requests will not be honored for units that do not consistently report according to these procedures.

4. Timing. Submit reports (Attachment 3) not later than Monday 1600 local time (local to the immunization clinic), describing events of the previous week (Sunday through Saturday). On Tuesday, the MILVAX Agency will compile these reports and provide a summary report to the Agency Director, with a copy to the DoD Office of General Counsel (OGC). Under a Court order, the Department of Justice will submit a weekly report to the Court on this matter. Any violations will be reported to the MILVAX Agency as soon as recognized, without waiting for the next report cycle.

JOHN. D. GRABENSTEIN
COL, MS
Director

**Attachment 1: Anthrax Vaccine Immunization Program (AVIP),
Emergency Use Authorization (EUA)**

Compliance Agreement

Commanding Officer (CO)/Officer-in-Charge (OIC): read, sign, return to Director, Military Vaccine Agency, fax: 703-681-4692, DSN 761-4692. NIPR: vaccines@otsg.amedd.army.mil. SIPR: otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX). Voice: 703-681-5101, DSN 761-5101. Director will return an acknowledgment letter, authorizing receipt of anthrax vaccine shipments.

I read and understand the (fill in applicable date) ____ May 05 message from my Service headquarters, describing requirements for anthrax vaccination under the Emergency Use Authorization issued by the Food & Drug Administration on 27 Jan 05. I recognize the 27 Oct 04 injunction against mandatory anthrax vaccination is still in effect.

Each of the items on the checklist (Attachment 2) has been fulfilled for our activity. I understand the weekly reporting requirements (Attachment 3). If the Military Vaccine (MILVAX) Agency does not receive a report on time, they may contact the people named below to obtain another copy.

For medical units: My staff has informed or reminded every healthcare worker with responsibilities for administering anthrax vaccinations (including immunization back-up technicians) of the importance of confirming desire to receive anthrax vaccine under terms of the Emergency Use Authorization before the actual injection. The final sequence involves ensuring the patient has signed the roster to acknowledge receiving the EUA trifold brochure, understands the right to refuse, and states they want to receive the anthrax vaccine. Immediately prior to administration of the anthrax vaccine (once site and vaccine are prepared) ask the patient 'Do you want to receive the anthrax vaccine?' If the patient confirms, administer it.

Our activity is ready to comply with the EUA conditions for anthrax vaccination. I accept responsibility for EUA-AVIP trifold distribution, education, and weekly reporting.

If I am assigned other duties and am no longer responsible for this program, I will notify the MILVAX Agency before departure. I will instruct my replacement to complete his or her own Compliance Agreement and forward it to the MILVAX Agency.

(printed name, title)

(signature)

(date)

DSN telephone:

E-mail address:

This agreement corresponds to immunization team(s) for the following unit, ship, activity, or vaccination clinic, specific name and address: Zip code: _____ - _____

The medical activity storing anthrax vaccine and administering the anthrax immunizations, medical activity name and address: Zip code: _____ - _____

Alternate points of contact (Name, DSN telephone number, email)

- 1.
- 2.
- 3.

**Attachment 2: Anthrax Vaccine Immunization Program (AVIP)
Emergency Use Authorization (EUA)**

Implementation Checklist

Date _____ Place where immunizations given _____

Installation/Ship _____ OIC / Commander _____

Ensure these items have been completed before giving anthrax vaccinations:

- [] 1. Collect all previous AVIP trifold brochures from 2004 or earlier and discard them. Do not retain them for future use. Be sure to remove obsolete trifolds from pamphlet racks in waiting rooms, on bulletin boards, intranets, etc.
- [] 2. Obtain sufficient EUA-AVIP trifolds dated 5 Apr 05 or later, enough to give a personal copy to each person to be vaccinated, one for each dose. Each anthrax vaccine shipment will include EUA-AVIP trifold brochures equal to the number of doses ordered. Additional color copies of these revised trifolds are available by emailing usammadoc@det.amedd.army.mil or at www.anthrax.mil/EUA.
- [] 3. Obtain EUA-AVIP briefing slides. Available from www.anthrax.mil/EUA. If you need these slides shipped to you in hard copy or on a CD-ROM, call 877-GET-VACC or send an email request to vaccines@otsg.amedd.army.mil, SIPRNET otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX).
- [] 4. Attachment 4 provides a prototype EUA-AVIP education roster. Use EUA-AVIP education rosters only confirm that each person to be offered anthrax vaccination received an EUA-AVIP trifold brochure before each dose. This roster will be captioned "I received an EUA trifold for anthrax vaccine" or words to that effect. Rosters will include printed or typed name and date EUA-AVIP trifold received. Retain these rosters with unit records for 1 year. **Do not** collect signatures accepting/declining vaccination on trifolds or any other document. Personnel **do not** sign that they accept or decline anthrax vaccination under EUA, only that they received the EUA-AVIP trifold brochure.
- [] 5. Coordinate with supporting medical activity or ensure organic medical support has required EUA-AVIP training for vaccinators and healthcare providers. Assure all vaccinators (primary and back-up), clinical supervisors of vaccinators, preventive medicine and public health staff, and relevant healthcare providers (e.g., allergy-immunology, ambulatory care, flight medicine, emergency care) are familiar with the clinical science for anthrax vaccine and EUA requirements. Use training course available at www.anthrax.mil/EUA. Annotate training records accordingly. Vaccinators acknowledge the content in the following materials:

- a. Service EUA-AVIP implementation message (available at www.anthrax.mil/eua). Army: 5 May 05. USCG: 12 May 05. USMC: 16 May 05. USAF: 20 May 05. Navy: 20 May 05.
 - b. EUA-AVIP healthcare provider briefing slides (with audio) at www.anthrax.mil/EUA (CDs with audio also available).
 - c. BioThrax package inserts: available with every vaccine vial or at www.bioport.com/AnthraxVaccine/Insert/AVAIInsert.asp.
 - d. EUA-AVIP trifold brochure dated 5 Apr 05 or later.
 - e. Reporting procedures for Vaccine Adverse Events Reporting System (VAERS, www.vaers.org).
 - f. Reasons for medical exemption from anthrax vaccination (e.g., serious allergic reactions to anthrax vaccination, moderate or severe illness, pregnancy, latex sensitivity, immune-suppressive conditions, Guillian-Barré syndrome, prior anthrax infection). The most effective way to identify early pregnancy is to ask discreetly for date of last menstrual period and whether the last menses was normal and on time. Offer pregnancy testing before any vaccination.
- [] 6. Assure copies of the US District Court's 27 Oct 04 Order and Opinion and the 6 Apr 05 modification are readily available at the place where immunizations are given, in case anyone asks to read it. Copies of the Order and Opinion will be shipped with the EUA-AVIP trifold brochures and is also available at www.anthrax.mil/EUA.
- [] 7. Understand criteria for eligibility for anthrax vaccination (Under Secretary of Defense (P&R) memo, 29 Apr 05; Service EUA-AVIP implementation messages, Army: 5 May 05. USCG: 12 May 05. USMC: 16 May 05. USAF: 20 May 05. Navy: 20 May 05. Available at www.anthrax.mil/EUA.
- [] 8. Understand the option to refuse, including both (a) the reasons why the military and civilian leadership of the Armed Forces strongly recommends vaccination, as well as (b) the requirement that no one can be ordered or forced to be vaccinated under the EUA.
- [] 9. Inform or remind every healthcare worker with responsibilities for administering anthrax vaccinations (including immunization back-up technicians) of the importance of confirming desire to receive anthrax vaccine under terms of the Emergency Use Authorization before the actual injection. The final sequence involves ensuring the patient has signed the roster to acknowledge receiving the EUA trifold brochure, understands the right to refuse, and states they want to receive the anthrax vaccine. Immediately prior to administration of the anthrax vaccine (once site and vaccine are prepared) ask the patient 'Do you want to receive the anthrax vaccine?' If the patient confirms, administer it.
- [] 10. Assure unit/activity/command has sufficient trained personnel with passwords to enter data on the same day as vaccination into immunization tracking system (e.g., MEDPROS, AFCITA, RAMIS/MRRS, SAMS, MRS, CHCS II). Or has a

plan to train these people expeditiously, and can assuredly record vaccinations on SF Form 601, DD Form 2766, Deployable Medical Record, PHS Form 731, or similar form.

- [] 11. Assure OIC or commander understands **weekly reporting requirements** regarding option to refuse. These reports go to the Military Vaccine Agency, at the direction of the Deputy Secretary of Defense.
- [] 12. Assure OIC or commander understands need for officer(s) not directly involved in the EUA-AVIP to perform spot checks of anthrax vaccination operations to assure the option to refuse can be freely exercised.
- [] 13. Assure logistics personnel have been trained in cold-chain management procedures, including prompt refrigeration of vaccines upon receipt. [Or freezing, in the case of *YF-Vax*, *Varivax*, and *FluMist*]. Alarm systems are used to protect large inventories.
- [] 14. Assess available inventory of anthrax vaccine (e.g., in medical logistics warehouse). Arrange for shipment of initial quantity of anthrax vaccine, but clinics may not take physical possession of the vaccine until Military Vaccine Agency provides email approval of the Compliance Agreement.

Reassess items on this checklist each week.

**Attachment 3: Anthrax Vaccine Immunization Program (AVIP)
Emergency Use Authorization (EUA)**

Weekly Report Template

MEMORANDUM FOR Director, Military Vaccine (MILVAX) Agency

Fax: 703-681-4692, DSN 761-4692. Voice 877-GET-VACC. DSN 761-5101

NIPR: vaccines@otsg.amedd.army.mil

SIPR: otsg.opscenter21opns@hqda-S.army.Smil.mil (Attention: MILVAX)

SUBJECT: Report of Compliance with Emergency Use Authorization (EUA) Conditions
for Anthrax Vaccine Immunization Program (AVIP)

1. Report for the week of Sunday, _____ 2005 through Saturday, _____ 2005:

[If the following sentence is true, submit it as your report. If the following sentence is not true, change the text to explain what occurred to make the proposed text untrue. Be sure to specify the number of people vaccinated without an option to refuse and be prepared to provide a list of their names.]

No one received anthrax vaccination against his or her will, or without being informed of the option to refuse, or otherwise in violation of the option to refuse, at this unit for this interval.

2. Remedy. [If applicable, describe here steps taken to prevent noncompliance with the EUA from happening again. If not applicable, state "not applicable."]

3. I certify the accuracy of this report to the best of my knowledge.

Name Title Date

If faxed, sign on line above. If emailed, send as scanned PDF document or from approving authority's or alternate official's email account.

Zip code (eg, APO): _____ - _____

Contact email: _____

Contact telephone #: _____

Activity/Unit/Ship: _____